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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/500,246	02/08/00	FOSTER	T 6231.N-CN1

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EXAMINER	
CHOI,F	
ART UNIT	**PAPER NUMBER**
1616	5

DATE MAILED: 11/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/500,246	Applicant(s) FOSTER ET AL.	
	Examiner Frank I Choi	Art Unit 1616	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-15 and 17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-15 and 17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-15, 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis (U.S. Pat. 5,288,496) in view of Herbert et al. (U.S. Pat. 5,654,008) and Okada et al. (4,652,441) for the reasons of record set forth in the prior Office Action and the further reasons below.

Lewis, Herbert et al. and Okada et al. were discussed in the prior Office Action and the same are incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. Applicant asserts that use of microparticles as delivery vehicles do not comprise any aspect of the claimed invention and that these delivery vehicles are nowhere suggested nor disclosed in the prior art reference. However, the limitations cannot be so narrowly interpreted. For instance "encapsulants" does not exclude microparticles. In light of the fact that a large list of possible dosage forms each of which encompass a broad range of dosage formulations is set forth, a conclusory statement that the prior art does not teach or suggest the claimed invention does not appear to be sufficient to overcome the rejection.

Contrary to Applicant's arguments, the prior art teaches both immediate and long-term release, as such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to have both so as to effect an immediate treatment or relief and treatment or relief over a period of time. (See Lewis, Column 6, lines 43-55, Herbert et al., Column 17, lines 47-55). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., discrete particles) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 26 USPQ2d 1057 (Fed. Cir. 1993).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1, 4-7, 10, 13-15, 17, 18, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al.

Stevens et al. teach a composition and method of treating animals by implanting pellets, both immediate release and controlled-release, containing antibiotics and hormones (Abstract, Column 6, lines 38-68, Column 7, lines 1-65).

The difference between the cited reference and the claimed invention is that the cited reference does not expressly disclose a composition and method comprising both immediate release and controlled-release pellets having the same active ingredient. However, the cited reference amply suggests the same as it is known in the art to prepare immediate release and controlled-release pellets and that different pellets may be administered at the same time. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use both with the expectation of obtaining immediate treatment or relief or an initial burst combined with extended treatment to cover any infection or condition which the immediate release pellet does not meet conveniently in a single injection.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Claims 1, 6-10, 13, 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rickey et al.

Rickey et al. teach a composition and method of treating animals by injecting microparticles, containing various active ingredients, for example, estradiol, and megestrol acetate (Column 13, lines 19-27). It is taught that the microparticles can be mixed by size or by

type so as to provide for the delivery of the active agent in a multiphasic manner (Column 13, lines 34-42, Column 17, lines 36-68).

The difference between the cited reference and the claimed invention is that the cited reference does not expressly disclose a composition and method comprising both immediate release and controlled-release components having the same active ingredient. However, the cited reference amply suggests the same as it is known in the art to prepare microparticles having different release rates. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use both with the expectation of obtaining immediate treatment or relief or an initial burst combined with extended treatment to cover any infection or condition which the immediate release microparticle does not meet conveniently in a single injection.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Claims 1, 4-7, 10, 13-15, 17, 18, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guittard et al.

Guittard et al. teach a composition and method of treating animals by implantation comprising an osmotic device having a immediate burst layer and a long-term release layer (Column 7, lines 1-44). Various materials are taught which are suitable for the immediate release layer (Column 12, lines 18-39). Various active ingredient are taught (Column 13, lines 50-68, Columns 14, 15, Column 16, lines 1-21).

The difference between the cited reference and the claimed invention is that the cited reference does not expressly disclose a composition and method comprising both immediate release and controlled-release components having the same active ingredient. However, the cited reference amply suggests the same as it is known in the art to prepare an osmotic device having different release rates. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use both with the expectation of obtaining immediate treatment or relief or an initial burst combined with extended treatment to cover any infection or condition which the immediate release layer does not meet conveniently in a single dosage form.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC
November 19, 2000

JOHN PAK
PRIMARY EXAMINER
GROUP 1600